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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/751,072 | 01/02/2004 | Sven Eyckerman | 2676-6264US | 2266 |

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| EXAMINER | |
|---|---|
| HOWARD, ZACHARY C | |
| **ART UNIT** | **PAPER NUMBER** |
| 1646 | |

| NOTIFICATION DATE | DELIVERY MODE |
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| 04/22/2008 | ELECTRONIC |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

USPTOMail@traskbritt.com

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/751,072 | EYCKERMAN ET AL. | |
| | Examiner | Art Unit | |
| | ZACHARY C. HOWARD | 1646 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *03 March 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1,3,11,13 and 16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,11,13 and 16* is/are rejected.

7)☒ Claim(s) *1* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *22 January 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Status of Application, Amendments and/or Claims*

The amendment after final filed on 3/3/08 under 37 C.F.R § 1.116 has been entered in full. Claims 4-8, 22 and 24-26 are canceled (claims 2, 9, 10, 12, 14, 15, 17-21 and 23 were previously canceled). Claim 1 is amended.

Claims 1, 3, 11, 13 and 16 are under consideration in the instant application.

### *Withdrawn Objections and/or Rejections*

The following page numbers refer to the previous Office Action (1/2/08).

All rejections of claims 4-8, 22 and 24-26 are moot in view of Applicants' cancellation of these claims.

The rejections of claims 1, 3, 11, 13 and 16 under 35 U.S.C. § 112, first paragraph at pg 2-12 for failing to provide enablement for the full scope of the claims, and at pg 12-15 for failing to comply with the written description requirement, are *withdrawn* in view of Applicants' amendments to the claims.

The objection to claim 1 at pg 16 is *withdrawn* in view of Applicants' amendments to the claim.

The rejection of claims 1, 3, 11, 13 and 16 under 35 U.S.C § 112, second paragraph, at pg 17 for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is *withdrawn* in view of Applicants' amendments to the claims.

### *Withdrawal of Finality*

In view of the new grounds of rejection presented herein, the finality of the previous Office Action is *withdrawn*.

### *New Objections and/or Rejections*

### *Claim Objections*

Claim 1 is objected to because of the following informalities:

(1) In the recitation of "a JAK-phosphatse" in line 12 of claim 1, the word "phosphatase" is misspelled.

Appropriate correction is required.

### *Claim Rejections – 35 USC § 102/103*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 3, 11, 13 and 16 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Eyckerman et al, 1999. Eur Cytokine Netw. 10(4): 549-546. It is noted that this publication shares 3 inventors in common with the instant application.

Eyckerman teaches recombinant receptors comprising the mouse leptin receptor with one or more tyrosine residue mutations in the cytoplasmic domain and a heterologous myc-tag polypeptide (pg 550, column 1; eight different receptors are disclosed each with different mutations). Eyckerman teaches that Tyr1138 is an activation site required for signaling in response to leptin binding ("Tyr to Phe mutations in the cytoplasmic tail of the mouse leptin receptor confirmed the critical role of Tyr1138 (a YxxQ motif) and STAT-3 activation for induction of leptin-induced genes in PC12"; see Abstract on pg 549). One of the mutant receptors taught by Eyckerman comprises two tyrosine mutations (Tyr985Phe and Tyr1077Phe) but retains the Tyr1138 activation site (pg 550). This is the same combination of mutations (Tyr985Phe and Tyr1077Phe) and wild type tyrosine (Tyr1138) as used in the LepRFFY receptor described in Example 1 of the instant application (see Figure 1). This receptor meets all of the

structural requirements of claim 1: "an extracellular ligand binding domain derived from a mammalian receptor" (e.g., mouse leptin receptor domain); a cytoplasmic domain comprising a domain derived from a cytoplasmic domain of a mammalian receptor (e.g., leptin receptor domain), at least one activation site that is a tyrosine residue (e.g., Tyr1138) and a heterologous bait polypeptide (e.g., the myc-tag), and wherein the cytoplasmic domain comprises at least a JAK binding site (Eyckerman teaches on page 549 that the leptin receptor includes a "a JAK tyrosine kinase binding site (Box 1)").

In addition to the above mentioned structural limitations, claim 1 contains the following functional limitation: "wherein the activation of said recombinant receptor is inhibited by binding of a fusion protein to said heterologous bait polypeptide, said fusion protein comprising a prey polypeptide and at least one of an inhibitor of the activation of said recombinant receptor that is selected from the group consisting of a member of the SOCS family, a JAK-phospatse [sic], and a STAT-phosphatase". Eyckerman teaches a receptor that meets all of the structural limitations of claim 1, but Eyckerman is silent as to whether the receptor has the functional limitation as claimed.

The examiner is unable to determine whether the prior art disclosure of the receptor taught by Eyckerman possesses the characteristic of being inhibited if contacted with a fusion protein polypeptide that binds to the heterologous bait polypeptide (myc tag) and comprises a prey polypeptide and a inhibitor of activation. With these conditions, where the product seems to be identical except that the prior art is silent to the characteristic or property claimed, then the burden shifts to applicant to provide evidence that the prior art would neither anticipate nor render obvious the claimed invention. Note the case law of *In re Best* 195 USPQ 430, 433 (CCPA 1977).

It is stressed that the claims are directed to a genus of recombinant receptors, wherein the scope of the genus is partly defined by a functional interaction with a genus of prey polypeptides. The claims are not directed to the prey polypeptide *per se*, either alone or in combination with receptor. As such, the rejection of claim 1 under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Eyckerman et al, 1999 does not require that Eyckerman actually teach a fusion protein capable of inhibiting the receptor. If the receptor described by Eyckerman is inherently

capable of being inhibited when contacted with a fusion protein comprising a prey polypeptide and an inhibitor of activation (a member of the SOCS family, a JAK phosphatase or a STAT phosphatase), then it meets the functional limitations of the claim. As far as the Examiner can determine, the mutant receptor described by Eyckerman would be inhibited if contacted with a fusion protein e such as those described in the instant application (e.g., one comprising both a prey polypeptide and an inhibitor of activation).

Claim 3 depends from claim 1 and recites an additional functional limitation that "said recombinant receptor is activated by addition of a compound that disrupts an interaction between said heterologous bait polypeptide and said prey polypeptide". As with claim 1 above, the examiner is unable to determine whether the prior art disclosure of the receptor taught by Eyckerman possesses the characteristic of being activated by addition of a compound that disrupts an interaction between the heterologous bait polypeptide and the prey polypeptide. With these conditions, where the product seems to be identical except that the prior art is silent to the characteristic or property claimed, then the burden shifts to applicant to provide evidence that the prior art would neither anticipate nor render obvious the claimed invention.

Claim 11 is directed to a vector encoding the recombinant receptor of claim 1. Eyckerman teaches vectors encoding the receptors described above (pg 550, column 1). Therefore, claim 11 is also included in this rejection.

Claim 13 encompasses a eukaryotic cell comprising the receptor of claim 1. Eyckerman teaches rat PC12 cells transformed with the vectors described above (pg 550, column 1). Therefore, claim 13 is also included in this rejection.

Claim 16 is drawn to a "cloning vector encoding a recombinant receptor" that comprises "a nucleotide sequence encoding a cytoplasmic domain of a mammalian receptor" comprising "at least one restriction site configured to allow an in frame fusion of a nucleic acid sequence encoding a bait polypeptide, wherein insertion of the nucleic acid sequence encoding said bait polypeptide results in the vector of claim 11". The vector sequence taught by Eyckerman already includes a 'bait polypeptide' (myc tag). However, the vector sequence inherently includes a restriction site near the C-terminus

of the sequence encoding the leptin receptor, which if used to insert a sequence encoding another polypeptide (myc tag or other) would result in a vector that would still meet the limitations of claim 11. For example, the nucleic acid sequence encoding the murine leptin receptor includes the sequence 'CTCAAG' near the C-terminus of the receptor (see the record for GenBank Accession NM_14616, 6 pages, printed 1/16/2008; cited here only as a teaching reference), which is a recognition sequence for the restriction enzyme SmlI. Therefore, claim 16 is also included in this rejection.

## ***Conclusion***

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachary C. Howard whose telephone number is 571-272-2877. The examiner can normally be reached on M-F 9:30 AM - 6:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary B. Nickol can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Z. C. H./
Examiner, Art Unit 1646

/Elizabeth C. Kemmerer/
Primary Examiner, Art Unit 1646